

REMARKS

Applicants respectfully request reconsideration and reexamination of the present application in light of the amendments and the remarks below. Claims 1-5 and 7 are pending in this application. Claim 6 has been cancelled.

Claims 1, 2, and 3 have been amended. These claim amendments are made to clarify the subject matter therein. Therefore, these amendments are submitted in order to place the claims in condition for allowance, and do not disclaim any subject matter to which the Applicants are entitled.

Rejection Under 35 U.S.C. § 102

The Examiner has maintained the rejection of claims 1, 2, and 5 under 35 U.S.C. § 102(b) as being anticipated by Rao, et al., (Cancer Epidemiol. Biomarkers Prev.) (Paper No. 20050610, pages 3-5 and 7-8). Applicants respectfully traverse this rejection.

As amended, the claims recite a method for identifying cancer cells and their precursors by simultaneously detecting at least two molecular markers in a single cell. That is, the method entails simultaneously detecting signal intensities of color mixtures resulting from the markers in a single cell and combining and accrediting the signal intensities. As exemplified in the enclosed figures, her2/neu was labeled with a green reagent ("Her2/neu-Fite") and p53 was labeled with a red reagent ("P53-Biotin"). As illustrated in Picture A, there are some cells that are labeled either red or green, and as such these cells are not considered positive. However, there are other cells that are labeled yellow reflecting "color mixture," and these cells are deemed positive. Picture B represents another view wherein the red cells are considered positive. Furthermore, as described on page 13, lines 16-19 of the specification, it is the intermixture (e.g., "red-brown") in a sample region that is of interest.

Rao, et al., do not teach the steps of simultaneously detecting signal intensities of color mixtures. That is, Rao, et al., measures each marker individually. For example, on page 1028, Oregon Green-labeled p53 is detected at excitation of 485 + 22 nm and Texas-Red-labeled G-actin is detected at excitation of 560 + 40 nm. Thus, Rao, et al., does not teach simultaneous detection.

Since Rao, et al., does not teach each and every limitation of the claimed invention, a proper rejection under 35 U.S.C. § 102(b) has not been established. Accordingly, Applicants respectfully request reconsideration and withdrawal of the of the present rejection.

The Examiner has maintained the rejection of claims 1, 3, 4, and 5 under 35 U.S.C. § 102(b) as being anticipated by McNamara, et al., (U.S. Patent No. 6,007,996) (Paper No. 20050610, pages 5-6 and 7-8). Applicants respectfully traverse this rejection.

As discussed, the claims recite a method for identifying cancer cells and their precursors by simultaneously detecting at least two molecular markers in a single cell, that is, the method entails simultaneously detecting signal intensities of color mixtures in a single cell.

McNamara, et al., do not teach simultaneously detecting signal intensities of color mixtures in a single cell.

Since McNamara, et al., does not teach each and every limitation of the claimed invention, a proper rejection under 35 U.S.C. § 102(b) has not been established. Accordingly, Applicants respectfully request reconsideration and withdrawal of the of the present rejection.

Rejection Under 35 U.S.C. § 103(a)

The Examiner has maintained the rejection of claim 7 under 35 U.S.C. § 103(a) as unpatentable over either Rao, et al., or McNamara, et al., in view of U.S. Patent No. 5,109,429 (Bacus, et al.) (Paper No. 20050610, pages 6-7). Applicants respectfully traverse.

As discussed, the claims recite a method for identifying cancer cells and their precursors by simultaneously detecting at least two molecular markers in a single cell, that is, the method entails simultaneously detecting signal intensities of color mixtures in a single cell.

Neither Rao, et al., nor McNamara, et al., teach or suggest simultaneously detecting signal intensities of color mixtures in a single cell.

The deficiencies of Rao, et al., and McNamara, et al., are not remedied by Bacus, et al. Bacus, et al., describes a kit, but does not describe a test kit that could be utilized to implement the claimed method. That is, Bacus, et al., do not teach simultaneously detecting signal intensities of color mixtures in a single cell.

Since the combination of references does not teach every element of the claimed invention, these references cannot be combined to support a rejection of the claims under U.S.C. § 103(a). MPEP § 2143.

It is therefore submitted respectfully that Rao, et al., and McNamara, et al., either singly or in combination with Bacus, et al., fails to teach or suggest the method as presently claimed, and that the current invention is novel and nonobvious in view of the prior art references.

For the foregoing reasons in this section, Applicants respectfully request reconsideration and withdrawal of the present rejections.

Double Patenting

The Examiner has rejected claims 1, 2, and 4-7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 6, 9, and 10 of co-pending Application No. 10/022,618 (Paper No. 20050610, pages 2-3).

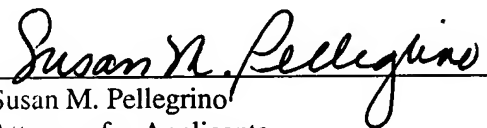
It remains unknown what subject matter claimed and disclosed in the present application will be deemed allowable; hence any statement regarding this rejection made on Applicants' part would be premature. Therefore, Applicants respectfully traverse this rejection, and request that this rejection should be held in abeyance until subject matter is deemed allowable in this application.

CONCLUSION

For the foregoing reasons, Applicants submit that the claims are in condition for allowance and Applicants respectfully request reexamination of the present application, reconsideration and withdrawal of the present rejections and objections, and entry of the amendments. Should there be any further matter requiring consideration, Examiner Cross is invited to contact the undersigned counsel.

If there are any further fees due in connection with the filing of the present reply, please charge the fees to undersigned's Deposit Account No. 13-3372. If a fee is required for an extension of time not accounted for, such an extension is requested and the fee should also be charged to undersigned's deposit account.

Respectfully submitted,

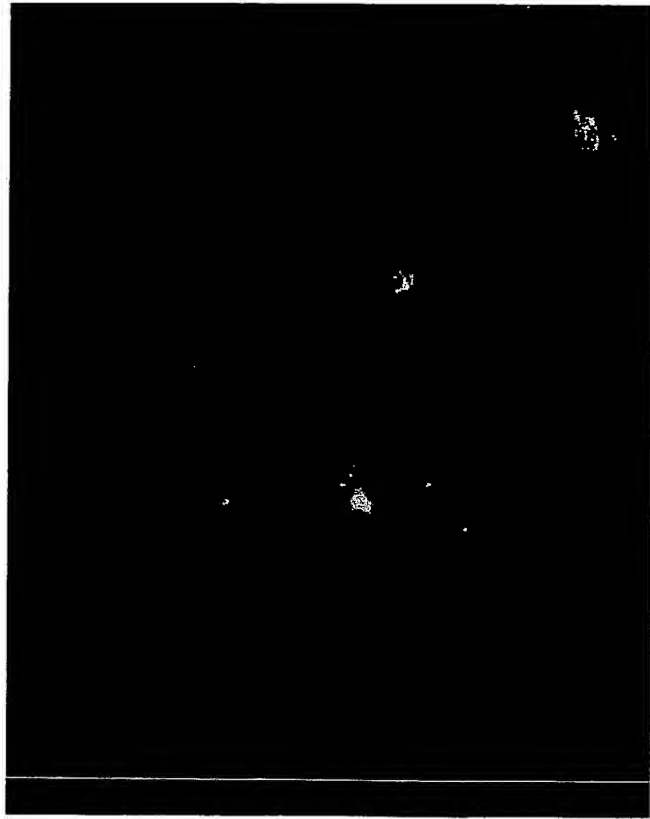

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Date: December 15, 2005

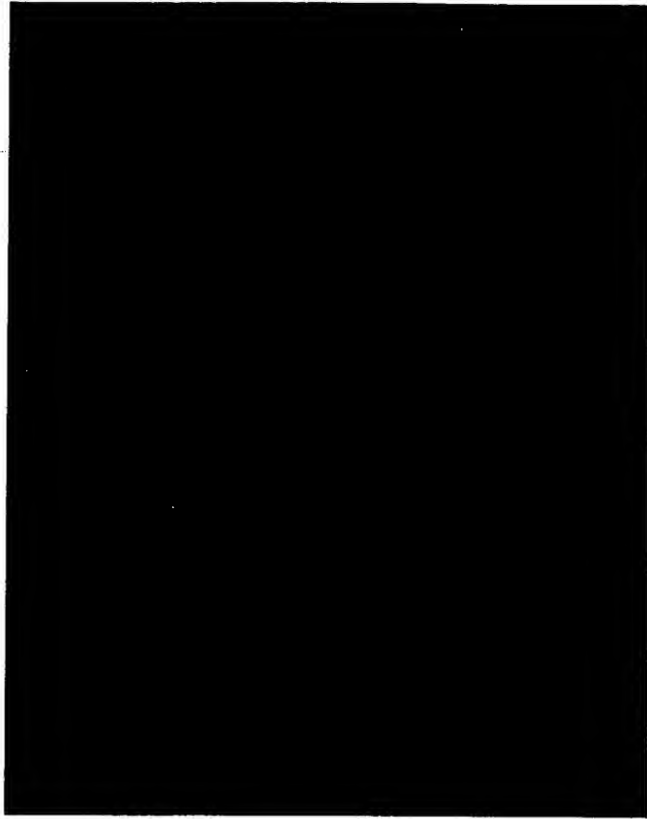
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Her2/neu-Fitc u. P53-Biotin



Picture A



Picture B

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